

**REMARKS**

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

**I. Claim Amendments**

By the foregoing amendments to the claims, claims 1, 2 and 14-16 have been amended as discussed below.

The amendments to the claims have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicant reserves the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments to the above-identified application is respectfully requested.

**II. Response to Claim Objection**

At page 2 of the Office Action, claim 1 has been objected to because the term "CD4 Bright low side scatter" should allegedly be written as "CD4<sup>Bright</sup>/low side scatter."

Claim 1 has been amended as required by the Examiner. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the claim objection.

**III. Response to Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

At pages 3-4 of the Office Action, claims 2, 14 and 16 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite for a number of reasons.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, Applicant has amended claims 1, 2 and 14 as suggested by the Examiner. In addition, claims 15 and 16 have also been amended to be consistent with claims 1, 2 and 14.

However, Applicant respectfully submits that the Examiner's comment on page of 3 of the Office Action that the performance of steps (a) and (b) on a hematology analyzer in claim 2 contradicts the flow cytometry method of claim 1 is incorrect. In the specification, a hematology analyzer and a flow cytometer are used in examples of a dual platform system (*i.e.* two instruments – a haematology analyzer and a flow cytometer) or a single platform

system (*i.e.* one instrument – a haematology analyzer only or a flow cytometer only) for enumerating the number of CD4+ lymphocytes in a cell sample. As appreciated by those skilled in the pertinent art, a hematology analyzer is one type of flow cytometer which typically measures cells flowing through a sensing zone by volumetric sensing (*i.e.* electronic measurements such as the Coulter principle) and optical measurement (*i.e.* not including fluorescence measurements). In addition, as described in the specification at page 8, paragraphs 1 and 4, hematology analyzers that make additional fluorescence measurements are also available. These latter hematology instruments are another type of flow cytometer that also measure cells flowing through a sensing zone. Still further, another type of flow cytometer has optical and fluorescence measurements without electronic measurements, yet it is still considered a flow cytometer because the instrument analyzes cells flowing through a sensing zone. Copies of two brochures describing hematology analyzers available from Mindray and Coulter, describing their respective instruments as flow cytometers or as using flow cytometry, are attached for the Examiner's reference.

To clarify the present invention, the claims have been further amended herein to recite an instrument which measures fluorescence. This amendment is supported in the specification, at least at page 8, paragraphs 1 and 4. To more clearly define the fluorescence measurement, Applicant has replaced the claim term "gate" with "discriminator." As noted on page 7 of the previous Amendment and Reply in response to the Office Action dated January 10, 2007, establishing a "gate" in the context of the present claims refers to establishing a discriminator between the cells of interest and the cells which are not of interest. Moreover, when using flow cytometers that measure fluorescence (*see* above), it would be readily appreciated by one of ordinary skill in the art that discrimination among cells can be accomplished by using a single parameter threshold or a two parameter measurement.

In view of the above, Applicant submits that the claims as amended herein particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the indefiniteness rejections.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Reply or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: March 11, 2008

By:

A handwritten signature in dark ink, appearing to read "Lisa E. Stahl", written over a horizontal line.

Lisa E. Stahl

Registration No. 56,704

P.O. Box 1404  
Alexandria, VA 22313-1404  
703 836 6620